No. 74-215

In the Supreme Court of the United States

OCTOBER TERM, 1974

UNITED STATES OF AMERICA, PETITIONER

v.

JOHN R. PARK

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF FOR THE UNITED STATES

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OPINION BELOW

The opinion of the court of appeals (Pet. App. 1A–12A) is reported at 499 F. 2d 839.

JURISDICTION

The judgment of the court of appeals was entered on July 2, 1974 (Pet. App. 13A). On July 26, 1974, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including August 30, 1974. The petition was filed on August 30, 1974, and granted on November 11, 1974 (A. 73). The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether, in a prosecution of a corporate officer for doing or causing acts resulting in the adulteration of food, an instruction that the jury may convict if it finds that the defendant had a responsible relation to the situation, but which does not also require a finding of particular acts of omission or commission or gross negligence by the officer, accords with the standards of *United States* v. *Dotterweich*, 320 U.S. 277.

2. Whether evidence that the president of a supermarket chain was on notice of insanitary conditions in his firm's Philadelphia warehouse in March 1970, was admissible to rebut his defense of justifiable reliance on subordinates, or to show his failure adequately to supervise them, with respect to insanitary conditions in the chain's Baltimore warehouse in 1971 and 1972.

STATUTES INVOLVED

Section 301(k) of the Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1042, as amended, 21 U.S.C. 331(k), provides:

The following acts and the causing thereof are prohibited:

* * * * *

> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce

> and results in such article being adulterated or misbranded.

Sections 303(a) and (b) of the Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1043, as amended, 21 U.S.C. 333(a) and (b) provide:

> (a) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.
>
> (b) Notwithstanding the provisions of subsection (a) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $1,000, or both.

Section 402(a) of the Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1046, as amended, 21 U.S.C. 342(a), provides in part:

> A food shall be deemed to be adulterated * * * (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health * * *

STATEMENT

A. THE PROCEEDINGS IN THE DISTRICT COURT

In a five-count information filed in the United States District Court for the District of Maryland, the United States charged Acme Markets, Inc., a large

food store chain,[1] and its president, John R. Park, with violating Section 301(k) of the Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. 331(k). The information alleged that the defendants had caused five lots of food which were being held for sale after shipment in interstate commerce to become adulterated "in that * * * [they] consisted in part of a filthy substance by reason of the presence in said food of rodent pellets, rodent hairs and by reason of being rodent gnawed * * * [and] in that said food was held under insanitary conditions whereby it may have become contaminated with filth" (A. 5). See 21 U.S.C. 342(a)(3) and (4) *supra,* p. 3.

Acme pleaded guilty to each count of the information. On May 10, 1973, after a jury trial, Park was found guilty on all five counts of the information and was subsequently sentenced to pay a total fine of $250.

At trial, the parties stipulated that the food lots involved had been shipped in interstate commerce and were being held for sale in the Baltimore warehouse (Tr. 34–38). A Food and Drug Administration (FDA) investigator testified that in the November–December 1971 inspection of the basement of the Baltimore warehouse (A. 20–21):

> We found extensive evidence of rodent infestation in the form of rat and mouse pellets throughout the entire perimeter area and along the wall.

[1] Acme is a nationwide chain with approximately 36,000 employees, 874 retail outlets, twelve main warehouses, and four special warehouses, located in various parts of the country. The company headquarters, including respondent's office, is located in Philadelphia, Pennsylvania (Pet. App. 5A).

> We also found that the doors leading to the basement area from the rail siding had openings at the bottom * * * large enough to admit rodent entry. There were also rodent pellets found on a number of different packages of boxes of various items stored in the basement, and * * * there were also broken windows along the rail siding.

On the first floor, the inspectors found (A. 22):

> Thirty mouse pellets on the floor along the walls and on the ledge in the hanging meat room. There were at least twenty mouse pellets beside bales of lime Jello and one of the bales had a chewed rodent hole in the product. We also saw two hundred mouse pellets in the perimeter area of the Jello storage area. There were several hundred rat and mouse pellets along walls and in corners and on pallets of wild bird food.

The evidence also established numerous other insanitary conditions such as rat and mouse urine and nesting material in and around food, live and dead rodents in the warehouse, liquid drain cleaners stored near cooked ham, extremely overcrowded conditions, and accumulated trash (A. 21–22; Gov't Exh. 4).

Following the inspection, Dr. Norman Kramer, Chief of Compliance of the FDA's Baltimore office, wrote to Park on January 27, 1972, advising him of the conditions at the Baltimore warehouse (A. 64). The letter specifically informed Park that the Baltimore warehouse was "actively and extensively inhabited by live rodents" and that these conditions had "obviously existed for a prolonged period of time without any detection, or were completely ignored." Dr. Kramer testified that he sent a copy of the letter

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to Robert W. McCahan, Acme's Baltimore Division Vice President, as "[o]ne of the head men of * * * [the Baltimore] operation" (A. 33). The others with responsibility he named were officials in the corporate headquarters in Philadelphia: Mr. Park, Acme's president; Mr. Fahlhaber, the vice president for engineering; Mr. Hammel, the executive vice-president for sales and operations; and Mr. Bronsdon, Acme's sanitary inspection engineer (A. 33, see A. 36; A. 49).[2]

In March 1972, FDA conducted a second inspection of the Baltimore warehouse. While the inspector noted some improvement in the sanitary condition of the warehouse, he also found further evidence of rodent infestation. The Baltimore warehouse still contained rodent nesting material, dead rodents, damaged liquid bait traps, poorly fitted exterior doors, and rodent-contaminated food products (A. 23).[3]

Acme's general counsel, Mr. Gilfillan, identified Park at trial as the president and chief executive officer of Acme and read the company bylaws describing Park's duties. The bylaws provide that the chief executive officer "shall, subject to the board

[2] On February 7, 1972, McCahan, upon the direction of Park, responded to the letter. McCahan's letter claimed that the warehouse and adjacent property were cleaned, increased efforts were made in baiting for rodents, the building was inspected and potential rodent entry points repaired, hazardous household products were relocated away from food products, and additional cleaning equipment was purchased and additional personnel hired to keep the warehouse clean (A. 66).

[3] The first four counts of the information (A. 4–9) described violations observed during the November and December 1971 inspection, while the fifth count described violations observed during the March 1972 inspection (*ibid.*).

of directors, have general and active supervision of the affairs, business, offices, and employees of the company." He testified that Park functions by delegating duties, but that Park was responsible for seeing that his appointees "all work together." He added that sanitation responsibilities were delegated to Mr. Fahlhaber and Mr. Bronsdon (A. 40–41).

At the close of the government's case-in-chief, respondent moved for a judgment of acquittal on the ground that "Mr. Park is not personally concerned in this Food and Drug violation." The trial court denied the motion, stating that *United States* v. *Dotterweich*, 320 U.S. 277, "still seems to be the last word in this area. Whatever I might think of it, it has not been changed by Congressional action. I assume that the Congress had not acted, knowing the results of that case. It seems to me that case would be controlling here and says, in effect, the ultimate judgment should rest with the jury" (A. 42).

Park was the only defense witness. He testified that, while all company employees were under his direction, he employed a system of delegated responsibilities under which he had assigned the responsibility for sanitation to various other persons within the corporation (A. 43–46). He admitted having read the January 27 letter sent to him by FDA advising him of the insanitary condition of the Baltimore warehouse and described the action he undertook in response to the letter as follows (A. 47):

> A. [Mr. Gilfillan, Acme's general counsel] told me that he had discussed the matter with Mr. McCahan and that Mr. McCahan was in-

vestigating the situation immediately and would be taking corrective action and would be preparing a summary of the corrective action to reply to the letter.

* * * * *

Q. Well, aside from what you did, or aside from what Mr. Gilfillan did for you, what could you have done? Is there anything you could have done?

A. I don't believe there was anything I could have done more constructively than what I found was being done.

Q. And you were satisfied with what was being done?

A. Yes, sir.

On cross-examination Park conceded that sanitation "is a thing that I am responsible for in the entire operation of the company" and stated that he assigned this phase of the company's operation to "dependable subordinates" (A. 48–49).

Park was then cross-examined with respect to, and admitted having read, a letter addressed to him from FDA regarding insanitary conditions in Acme's Philadelphia warehouse in March of 1970.[4] In that letter (Gov't Exh. 27, A. 70–71), dated April 24, 1970, Park was advised that discarded paper and other debris providing potential rodent harborage, ill-fitting doors providing potential rodent entryways, and "[r]odent nesting, rodent excreta pellets, rodent stained bale bagging and rodent gnawed holes" had been observed at Acme's Philadelphia warehouse. Park acknowledged

[4] Counsel for Park objected to all questions concerning the Philadelphia incident (A. 51).

that, with the exception of the divisional vice-president, the same corporate officials have responsibility for sanitation in both Baltimore and Philadelphia (A. 54–55).

Park then described his responsibilities with respect to the insanitary conditions as follows (A. 55):

Q. And after the same problem occurred twice, once in Philadelphia and once in Baltimore, did you have any reason to believe that the system you had set up of handling sanitation, the responsibilities you had delegated to others for sanitation, that system just wasn't working, sir?

A. Well, the fact that this occurrence occurred in Baltimore indicated that it wasn't working perfectly.

Q. If a system was set up and wasn't working, who was responsible for that, sir?

A. In Baltimore, I would hold Mr. McCahan responsible.

Q. Who set up the system, sir?

A. The organizational structure has been evolved over a good many years. Actually, I am responsible for the entire organizational structure.

Q. And if a system that is set up and it doesn't work, you are responsible for changing it, is that corect?

A. For any result which occurs in our company, I am ultimately the chief executive officer and, therefore, responsible.

The government's theory of the case, as stated in summation, was that "Mr. Park was responsible for seeing that sanitation was taken care of, and he had a system set up that was supposed to do that. This

system didn't work. It didn't work three times. At some point in time, Mr. Park has to be held responsible for the fact that his system isn't working * * *" (A. 60).

The district court instructed the jury on the issue of respondent's responsibility as follows (A. 61–62):

> The main issue for your determination is * * * whether the Defendant held a position of authority and responsibility in the business of Acme Markets.
>
> The corporation, Acme Markets, Incorporated, has already entered a plea of guilty to the charge placed against it, and, while that plea does not imply, in any way, the Defendant Park is guilty, the fact that the materials in question are foods held for resale after shipment in interstate commerce and held under unsanitary conditions are issues that are beyond question in the case and must be accepted by you.
>
> The statute makes individuals, as well as corporations, liable for violations. An individual is liable if it is clear, beyond a reasonable doubt, that the elements of the adulteration of the food as to travel in interstate commerce are present. As I have instructed you in this case, they are, and that the individual had a responsible relation to the situation, even though he may not have participated personally.
>
> The individual is or could be liable under the statute, even if he did not consciously do wrong. However, the fact that the Defendant is president[5] and is a chief executive officer of the Acme Markets does not require a finding of guilt. Though, he need not have personally participated in the situation, he must have had a responsible relationship to the issue. The issue is, in this case, whether the Defendant, John R. Park, by virtue of his position in the company, had a position of authority and responsibility in the situation out of which these charges arose.[6]

[5] Although the transcript says "present," the court obviously meant, and presumably said, "president."

The jury found Park guilty on all counts.

B. THE DECISION OF THE COURT OF APPEALS

A divided panel of the court of appeals reversed. The majority believed the government to be arguing "that the conviction may be predicated solely upon a showing that the defendant, Park, was the President of the offending corporation" (Pet. App. 4A). The court held that "a finding of guilt must be predicated upon some wrongful action by Park. That action may be gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission or omission which could 'cause' the contamination of the food" (Pet. App. 5A–6A). The court concluded that Park's conviction must be reversed because the jury instruction "might well have left the jury with the erroneous impression that Park could be found guilty in the absence of 'wrongful action' on his part" (Pet. App. 5A).

[6] Counsel for Park submitted only two requests for charge:

(1) "Statutes such as the ones the Government seeks to apply here are criminal statutes and should be strictly construed," and (2) "The fact that John Park is President and Chief Executive Officer of Acme Markets, Inc. does not of itself justify a finding of guilty under Counts I through V of the Information." The latter of these, in substance, was given by the court (*supra*).

The court also held that evidence concerning the Philadelphia incident was unduly prejudicial and should not have been admitted (Pet. App. 8A). The court nevertheless suggested that the evidence might be admissible at retrial depending upon "the prosecution's new approach to the presentation of its case" (Pet. App. 9A) and the district court's application of the standards for admission of evidence of prior offenses set forth in *United States* v. *Woods*, 484 F. 2d 127, 134 (C.A. 4).

Judge Craven dissented on the ground that "this case is controlled by *United States* v. *Dotterweich*, 320 U.S. 277 (1943)" (Pet App. 9A). He explained (Pet. App. 10A):

> * * * Park was not just 'remotely entangled' in the proscribed adulteration. Like Dotterweich, he was president of the corporation with full power to control its operations and to take measures to prevent rat infestation of food. Although he had delegated the day-to-day supervision of sanitation to subordinates, Park retained both the power and responsibility to see that the system of rodent control was effective, and if it didn't work, to change it.

He noted that the government had made "no effort to equate the presidency of the corporation with the responsibility. Instead the government argued that Mr. Park was responsible because he had established a system of rodent control that did not work in March 1970, November 1971 and March 1972 and that even so he made no effort to change or improve the system" (Pet. App. 11A; footnote omitted). Finally, he stated that, if FDA is required to show that Park

"acted wrongfully," evidence of prior violations would clearly be admissible or FDA could not possibly sustain its new burden of proof (Pet. App. 12A).

INTRODUCTION AND SUMMARY OF ARGUMENT

The Federal Food, Drug, and Cosmetic Act of 1938 is "a principal example" of legislation imposing "the highest standard of care on distributors * * *" (*Smith* v. *California*, 361 U.S. 147, 152). "[T]o stimulate proper care" (*United States* v. *Balint*, 258 U.S. 250, 253) "distributors of food * * * [are made] the strictest censors of their merchandise" (*Smith* v. *California*, *supra*, 361 U.S. at 152).

This high standard of care, and correlative strict liability, is of crucial importance to the public health because the Act's criteria of criminal liability, embodied in the provisions at issue here, govern the distribution of drugs and medical devices as well as food, and the adulteration, contamination or mislabeling of such products may have fatal or other serious consequences. Accordingly, laws of the kind involved here punish not only willful violations but also "neglect where the law requires care, or inaction where it imposes a duty." *Morissette* v. *United States*, 342 U.S. 246, 255.

1. *United States* v. *Dotterweich*, 320 U.S. 277, establishes that individual corporate officers and employees, as well as corporations, may be convicted for doing or causing the acts prohibited in Section 301 of the Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. 331. In that decision, this Court also restated

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the standard of responsibility for the corporate officers and agents through whom corporations handling food and drugs must act: those standing in a responsible relation to the prohibited acts may be criminally liable for failure to take steps to prevent their occurrence, even though the officers are not aware of wrongdoing.

Because corporate officers having managerial, policy-making or supervisory functions "have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers * * *" (*United States* v. *Dotterweich, supra,* 320 U.S. at 285), they are under an affirmative duty to be informed about, and to correct, conditions that violate the Act. Such a corporate officer is made criminally responsible for insanitary conditions because, "if he does not will the violation, [he] usually is in a position to prevent it with no more care than society might reasonably expect and no more exertion than it might reasonably exact from one who assumed his responsibilities" (*Morissette* v. *United States, supra* 342 U.S. at 256).

While the liability created by the 1938 Act is strict, it is not vicarious. The limits of the principle appear in its articulaton: the corporate officer must stand in a responsible relation to the prohibited acts; a claim that he is "powerless" may "be raised defensively at a trial on the merits." *United States* v. *Wiesenfeld Warehouse Co.,* 376 U.S. 86, 91.

In sum, officials of the business entities which affect the public health are subject to the highest standard of public accountability. This standard has protected the public since the Pure Food and Drugs Act of 1906, 34 Stat. 768; it was carried forward in the 1938 Act,

and it has stood unchanged to this day. The decision of the court of appeals in this case, however, would lower this standard by requiring proof that the responsible corporate official took "wrongful action," by which the court meant an affirmative showing of acts of "gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission or omission which would 'cause' the contamination of the food" (Pet. App. 6A). As *Dotterweich* shows, however, a corporate official "causes" a violation of the Act whenever he stands in a "responsible relation" to the prohibited condition and fails to take action to prevent or correct it.

The error of the court of appeals in requiring affirmative "wrongful action" by a corporate official is compounded by the fact that the court has read its decision in this case as making actual knowledge of the specific facts concerning a violation an element of responsibility. In *United States* v. *Abbott Laboratories,* C.A. 4, No. 74–1230, decided October 2, 1974, petition for a writ of certiorari pending, No. 74–699, the court, citing its decision in this case, stated that individuals who shared "in the responsibility of distributing adulterated or misbranded drugs in interstate commerce are potentially criminally liable" (slip op., p. 20).[7] The court then explained (*ibid.*):

[7] *Abbott* involved a criminal prosecution under Section 301 of the Act against Abbott Laboratories and five of its employees. The district judge dismissed the indictment because he believed there was prejudicial pretrial publicity and because he believed the grand jury was exposed to "prejudicial and inflammatory" information (slip op., p. 18). This court of appeals reversed.

> "Responsibility" in turn depends upon knowledge, and if knowledge is established it depends further on the action or non-action of the officer or employee after he has obtained knowledge.

This interpretation is contrary to *Dotterweich,* for, as the court of appeals recognized in this case, under *Dotterweich* "21 U.S.C. §§ 301–392 'dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing'" (Pet. App. 4A, quoting 320 U.S. at 281).

The legislative history confirms *Dotterweich's* interpretation of the 1938 Act. The criminal provisions of the Pure Food and Drugs Act of 1906 did not require proof of either knowledge or intent. This standard of criminal liability was carried forward in the 1938 Act, which was designed "to enlarge and stiffen the penal net." *Dotterweich, supra,* 320 U.S. at 282. Indeed in 1948, after *Dotterweich* had been decided, Congress explicitly rejected an attempt to limit criminal liability to offenses committed "willfully or as a result of gross negligence."

Congress and this Court in *Dotterweich* recognized that the strict standard of liability of the 1938 Act could operate harshly, or even unfairly, and that FDA should therefore exercise reasonable discretion in pursuing criminal prosecutions. It has, accordingly, been FDA policy to limit prosecutions to continuing violations, violations of an obvious or flagrant nature, and intentionally false or fraudulent violations. Prosecution of individual corporate officials is confined to those in a "responsible relation" to the offense; that is, officials who have the power and responsibility to prevent or discover and correct violations and fail to do so.

The prosecution of Acme and Park was in conformity with these guidelines. The rodent infestation of the Baltimore warehouse was a serious and continuing violation. Moreover, Park, although not required by *Dotterweich,* had actual notice from FDA of the problem and failed to correct it.

The decision below, limiting the liability of corporate officials to cases of "wrongful action," would seriously undermine Congress' efforts to protect the public health by imposing criminal liability on distributors of adulterated food and drugs, without regard to wrongful acts or knowledge of violations, "in order to stimulate proper care * * *." *United States* v. *Balint, supra,* 258 U.S. at 253. That interpretation would, moreover, tend to defeat the purpose of Congress by inviting corporate executives to insulate themselves from active supervision of matters vitally affecting the public health. Moreover, the standard adopted by the court of appeals would impose an unrealistic and impractical burden of proof on the government, since, even where an official knows of the problem in general terms, it may be impossible to prove that he knew of the actual contamination of a particular lot of food.

2. The evidence of prior insanitary conditions in the Philadelphia warehouse was admissible to rebut Park's defense that he justifiably relied on his subordinates. Since the same subordinates were involved in the Philadelphia violation, the April 1970 letter to Park tended to show that he had prior notice that his

subordinates were not taking adequate measures to prevent and correct insanitary conditions.

ARGUMENT

I. THE FOOD, DRUG, AND COSMETIC ACT IMPOSES CRIMINAL LIABILITY ON CORPORATE OFFICIALS WITH A "RESPONSIBLE RELATION" TO SANITATION WHO FAIL TO TAKE AFFIRMATIVE ACTION TO PREVENT INSANITARY CONDITIONS

A. UNDER THIS COURT'S DECISIONS, THE ACT IMPOSES CRIMINAL LIABILITY ON RESPONSIBLE CORPORATE OFFICIALS WHO FAIL TO PREVENT INSANITARY CONDITIONS, EVEN IN THE ABSENCE OF DELIBERATE WRONGDOING

Congress' intention to impose strict criminal liability for violations of Section 301, 21 U.S.C. 331, is apparent in the Act's penalty provisions. Section 303(a) makes a first violation of Section 301 a misdemeanor; Section 303(b) makes either a second violation, or a violation committed "with the intent to defraud or mislead," a felony. Section 303(c) provides for immunity in certain cases, not including insanitary warehouse conditions, in which goods have been received or delivered in good faith. 21 U.S.C. 333(a), (b) and (c). The fact that a first offense with intent to defraud or mislead is subject under Section 303(b) to heavier penalties than are prescribed under Section 303(a) for a first offense without such intent, shows that wrongful action and knowledge are not elements under Section 303(a). See S. Rep. No. 493, 73d Cong., 2d Sess., p. 20 (discussed *infra,* p. 28). Similarly, the carefully defined conditions under which good faith establishes immunity under Section 303(c) strongly indicate a legislative purpose to impose liability, notwithstanding good faith, in all other cases falling under Section 303(a). This interpretation was confirmed by this Court in *United States* v. *Dotterweich, supra,* and reaffirmed in *United States* v. *Wiesenfeld Warehouse Co.,* 376 U.S. 86, 91.

The *Dotterweich* case involved prosecution under Section 301 of a drug jobbing corporation, and its president and general manager, Dotterweich, for shipping misbranded and adulterated drugs in interstate commerce. A jury failed to convict the corporation, but nevertheless convicted Dotterweich as the responsible corporate officer even though he had no personal knowledge of the misconduct involved.[8] Despite the plain language of the statute, the court of appeals set aside the conviction, reasoning that liability should be confined to the corporation as a proprietor, and should not be extended to the individual agents through which it acts, because only the corporate principal could obtain a guaranty from its suppliers that their products were not adulterated or misbranded.[9] *United States* v. *Buffalo Pharmacal Co.,* 131 F. 2d 500 (C.A. 2).

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[8] The defendant was not personally involved in any of the shipments in question and had no knowledge of them when they were made. He did not examine any drug orders when they were received because these orders were processed automatically by his firm's shipping department according to established company procedures. The defendant was in general charge of the business, however, and was responsible for the firm's system of operations (Record On Appeal No. 44-2841, O.T. 1943, pp. 128-129, 144, 159).

[9] Such a guaranty, received in good faith, establishes immunity under Section 303(c), 21 U.S.C. 333(c).

This Court reversed the judgment of the court of appeals and reinstated Dotterweich's conviction. It held that the liability defined by the statute was not limited to corporations or other proprietors in a position to obtain immunity through the guaranty provisions of Section 303(c). On the contrary, the statute "casts the risk that there is no guaranty upon all who according to settled doctrines of criminal law are responsible for the commission of a misdemeanor." 320 U.S. at 284.

The Court explained that the Act "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in a responsible relation to a public danger. *United States* v. *Balint,* 258 U.S. 250." 320 U.S. at 281.

The 1938 Act makes responsible corporate officials criminally liable for failure to discover and correct insanitary conditions because they have the power and responsibility to prevent such conditions, and have failed to do so. The imposition of this strict standard of liability is based on the fact that responsible corporate officials have at least the opportunity to learn of, correct or prevent, insanitary conditions, whereas even the most scrupulous careful consumer is helpless against them. As the Court explained in *Dotterweich, supra,* 320 U.S. at 284–285:

> Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who

> have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.

See also *Morissette* v. *United States, supra,* 342 U.S. at 256.[10]

Thus certain corporate officials are under a duty to seek out and prevent insanitary conditions, and are made criminally liable for "inaction where * * * [the law] imposes a duty" (*id.* at 255). The duty thus imposed was intended to make "the distributors of food the strictest censors of their merchandise * * *" (*Smith* v. *California, supra,* 361 U.S. at 152). It requires the responsible officials to keep informed as to conditions which might violate the act, and bars them from claiming ignorance as a defense when violations within their zone of responsibility occur. See *United States* v. *Balint, supra,* 258 U.S. at 252–253; *Smith* v. *California, supra,* 361 U.S. at 152.

This duty is imposed only upon those "standing in responsible relation to a public danger," *United States* v. *Dotterweich, supra,* 320 U.S. at 281. This criterion limits the liability of corporate officials to those individuals whose functions within the corporation impose on them a duty to be informed, and who have power to initiate preventive measures or to order corrections.

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[10] The Court has subsequently relied upon *Dotterweich* not only in *Wiesenfeld, supra,* 376 U.S. at 91, but also in *United States* v. *Freed,* 401 U.S. 601, 609, in which it upheld the standard of criminal liability imposed by the National Firearms Act.

In *Dotterweich* the Court characterized the responsible relationship as follows (320 U.S. at 284): "The offense is committed, unless the enterprise which they are serving enjoys the immunity of a guaranty, by all who do have * * * a responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs." The Court explained, however (*ibid.*): "Whether an accused shares a responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission—assuming the evidence warrants it—to the jury under appropriate guidance." The Court added (*id.* at 285): "In such matters the good sense of the prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted."

The concept of responsible relation thus serves to limit the application of the Act to those corporate officials who have the power and responsibility to prevent or correct insanitary conditions, but fail to do so. The same objective is served by allowing an apparently responsible corporate official to prove—as a matter of defense—that he is without power to affect the prohibited condition. This is shown by *United States* v. *Wiesenfeld Warehouse Co., supra,* in which a warehouse company was charged under Section 301 (k) with holding food under conditions similar to those charged in the instant case. The defendant argued that the government was "seeking to impose criminal sanctions upon one 'who is, by the very nature of his business powerless' to protect against this kind

of contamination, however high the standard of care exercised." 376 U.S. at 91. The Court held: "Whatever the truth of this claim, it involves factual proof to be raised defensively at a trial on the merits" (*ibid.*).

Thus, under *Dotterweich* and *Wiesenfeld,* whether an individual bears a "responsible relation" to the offense is for the jury to determine in the light of his functions within the corporation and such defensive matters as he may raise at trial bearing on his power with respect to the violation.

The holding of the court of appeals in the present case would substantially distort this statutory scheme. The court recognized that under the Act the government need not prove "awareness of some wrongdoing" (Pet. App. 4A, quoting *Dotterweich,* 320 U.S. at 281). However, the court concluded that in prosecuting Park, as the responsible corporate officer, "the Government has confused the element of 'awareness of wrongdoing' with the element of 'wrongful action;' *Dotterweich* dispenses with the need to prove the first of those elements but not the second" (Pet. App. 4A; footnote omitted). And, noting that Section 301(k) prohibits "causing" adulteration, it defined " 'wrongful action' in this context as acts of the accused which *cause the* adulteration of such food" (Pet. App. 4A, n. 4; emphasis in original).

As *Dotterweich* shows, however, a corporate official "causes" a violation of the Act whenever he stands in a "responsible relation" to the prohibited condition and fails to take action to prevent or correct it. He may violate the Act by "inaction where it imposes a

duty" (*Morissette* v. *United States, supra,* 342 U.S. at 255); affirmative "wrongful action" by the accused is not required.

The jury instructions in *Dotterweich,* which were approved by this Court (320 U.S. at 285), clearly show that proof of a wrongful act by a corporate official is not necessary to establish his liability under Section 301.[11] These instructions did not require the jury to find "wrongful action" by the defendant, but simply to determine responsibility. Similarly, the charge in the instant case instructed the jury to determine whether Park "had a position of authority and responsibility in the situation out of which these charges arose." Statement, *supra,* p. 10–11.

As Judge Craven recognized in dissenting below, the government has never argued that Park is guilty of violating Section 301 solely because he is president of the corporation. And the trial judge carefully noted in his instructions (Statement, *supra,* p. 10–11). that corporate titles do not necessarily prove

[11] The district court in the *Dotterweich* case instructed the jury as follows:

"We also have as a defendant here, Joseph Dotterweich. As far as the question of his guilt regarding the charges in the information is concerned, the question is, if you find the product to be misbranded and adulter'ed, 'Was he responsible for the shipment of them in interstate commerce?' In other words, are you satisfied from the evidence that the shipment of the cascara compound and the shipment of the digitalis were made under his supervision by him as 'General Manager.' It is not necessary for the Government to prove that he personally and physically made the shipment himself. It is sufficient if the evidence establishes to your satisfaction that it was made under authority conferred by him as general manager upon his subordinates, including the receiving and shipping clerk." Record on Appeal No. 44–2841, O. T. 1943, p. 164. See, also, *United States* v. *Kaadt,* 171 F. 2d 600, 604 (C.A. 7).

responsibility for the situations resulting in violation of the Act. Rather, the government must offer proof of actual supervisory responsibility relating to the prohibited conditions. It was for the jury to determine in the light of that proof and the defendant's exculpatory evidence whether he was in fact responsible.

The error of the court below in requiring proof of "wrongful action" by the defendant is compounded by that court's subsequent decision in *United States* v. *Abbott Laboratories, supra.* In its decision in the present case, the court at least purported to recognize that the 1938 Act "dispenses with * * * awareness of some wrongdoing" (Pet. App. 4A). In *Abbott Laboratories,* however, the court held that "responsibility" under the Act "depends upon knowledge, and * * * on the action or nonaction of the officer or employee after he has obtained knowledge" (slip op., p. 20). In this more recent explication of its view of the 1938 Act, the court of appeals has, in effect, repudiated the holding of *Dotterweich, supra.*

Dotterweich defines standards of corporate and individual responsibility which are fundamental in the food and drug industries. They have been applied in numerous cases. For example, in *United States* v. *H. B. Gregory Co.,* 502 F. 2d 700 (C.A. 7), petition for a writ of certiorari pending, No. 74–142, the Court of Appeals for the Seventh Circuit expressly rejected a contention that the strict and personal liability defined by *Dotterweich* was an improper legal standard because it "fails to require a casual relation between the individual and the violation of the Act." 502 F. 2d at 705. Accord, *United*

States v. *Shapiro*, 491 F. 2d 335–337 (C.A. 6); *Lelles* v. *United States*, 241 F. 2d 21, certiorari denied, 353 U.S. 974; *United States* v. *Cassaro Inc.* 443 F. 2d 153, 157 (C.A. 1); *United States* v. *Kaadt*, 171 F. 2d 600 (C.A. 7); *United States* v. *Parfait Power Puff Co.*, 163 F. 2d 1008 (C.A. 7), certiorari denied, 332 U.S. 851; *United States* v. *Diamond State Poultry Co.*, 125 F. Supp. 617 (D. Del.).

B. THE LEGISLATIVE HISTORY CONFIRMS THIS COURT'S INTERPRETATION OF THE 1938 ACT

The standard of care and the criteria of criminal responsibility enunciated in *Dotterweich* and *Wiesenfeld* are those intended by Congress. That *Dotterweich* correctly construed the 1938 Act may be seen both from the legislative history of that Act and from Congress' actions subsequent to *Dotterweich*.

The first general federal statute prohibiting the adulteration and misbranding of foods and drugs, the Pure Food and Drug Act of 1906, established a strict standard of criminal liability. The criminal provision of the 1906 Act did not require proof of either knowledge or intent as an element of the criminal offense, and numerous cases held that it was intended to impose strict criminal liability upon both corporations and individuals.[12]

[12] See, e.g., *United States* v. *36 Bottles of London Dry Gin*, 210 Fed. 271 (C.A. 3); *Von Bremen* v. *United States*, 192 Fed. 904 (C.A. 2); *United States* v. *Mayfield*, 177 Fed. 765 (D. Ala.); *United States* v. *Buffalo Cold Storage Co.*, 179 Fed. 865 (W.D.N.Y.). See, generally, cases collected in White and Gates, *Decisions of Courts in Cases under the Federal Food and Drugs Act* (1934).

Despite this strict standard of liability, Congress began its work on the 1938 Act with an express concern that the penalties imposed under the 1906 Act had failed to secure compliance with the law. As the 1934 Senate Report on S. 2800 stated (S. Rep. No. 493, 73d Cong., 2d Sess., p. 20):

> The penalties provided under the present Food and Drugs Act have proved wholly inadequate to bring about substantial compliance with the law on the part of those manufacturers who regard an occasional small fine as an inexpensive license to carry on their illicit operations.[13]

Thus the 1938 Act was designed "to enlarge and stiffen the penal net." *United States* v. *Dotterweich*, *supra*, 320 U.S. at 282.

Congress' discussion of the penal provisions of the 1938 Act make it clear that the strict standard of liability in the 1906 Act was carried forward in the

[13] The original version of what eventually became the 1938 Act, S. 1944, 73d Cong., 1st Sess., and a similar bill, S. 2800, 73d Cong., 2d Sess., were initially referred to the Senate Committee on Commerce for hearings. After a series of hearings and a report, S. Rep. No. 493, 73d Cong., 2d Sess., the proposed legislation was revised and further hearings were held in both Houses of Congress. Meetings were also held with various representatives of the food, drug and cosmetic industries. After more than three years of congressional hearings, floor debates and discussions with consumer and industry representatives concerning various bills and proposals, committees in both Houses filed reports recommending adoption of S. 5, 75th Cong., 1st Sess. See S. Rep. No. 152, 75th Cong., 1st Sess.; H. Rep. No. 2139, 75th Cong., 3d Sess. After differences between the House and Senate versions of the bill were resolved by a Conference Committee, the bill was enacted into law. The legislative history of the 1938 Act is contained in Dunn, *Federal Food, Drug, and Cosmetic Act: A Statement of Its Legislative Record* (1938).

new law. Thus, the Senate Report on S. 2800 stated (S. Rep. No. 493, 73d Cong., 2d Sess., p. 20):

> Under the existing law the willful violator stands on the same plane with the party who inadvertently violates the law through the negligence of his employees. Paragraph (c) will place willful violators in a special category subject to heavier penalties than those who violate the law through inadvertence, carelessness, or negligence.

Though the proposal that eventually became the 1938 Act was revised substantially during the years it was pending before Congress, the distinction, adverted to in the Senate Report, between the penalties for willful and nonwillful violations, was retained in the final bill. The legislative history of these provisions thus establishes that Congress intended to continue to impose criminal liability on corporate officials for violations of the Act, even if they did not personally order or personally commit the offense.[14]

[14] The Senate Commerce Committee deleted from section 2(f) of S. 5, 75th Cong., 1st Sess., language which would have limited criminal liability to corporate officers "who personally ordered or did any of the acts constituting, in whole or in part * * *" violations of the Act. See Dunn, *Federal Food, Drug, and Cosmetic Act: A Statement of Its Legislative Record*, p. 657 (1938). Although the committee did not specifically explain why it deleted this particular language (see S. Rep. No. 91, 75th Cong., 1st Sess.; S. Rep. No. 152, 75th Cong., 1st Sess.), it is reasonable to infer that Congress intended to impose a standard of criminal liability on corporate officers at least as broad as that recognized in the 1906 Act. *See Dotterweich*, *supra*, 320 U.S. at 282.

Congress also deleted, as unnecessary, Section 12 of the 1906 Act which provided that "the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person." (*Id.* at 281–282) As the Court said in *Dotterweich*, *supra*, 320 U.S. at 282, "By 1938, legal understanding and practice had rendered such statement of the obvious superfluous."

Following this Court's decision in *Dotterweich*, hearings were held in Congress at which it was suggested that some proof of knowledge or intent should be required before criminal sanctions could be imposed.[15] This suggestion was opposed not only by FDA and various members of Congress but also by Mr. Charles Wesley Dunn who testified on behalf of the Grocery Manufacturers of America, the American Pharmaceutical Manufacturers Association and the New York State Bar Association. He stated:

> It has always been the situation under the Food and Drug law, and the law of unfair competition in the Federal Trade Commission Act, that intent is not an essential ingredient of the offense. If you make it so, you simply nullify, in effect, the practical value of these laws.

Hearings before a subcommittee of the Senate Committee on Interstate and Foreign Commerce on S. 1190 and H.R. 4071 80th Cong., 2d Sess., p. 49. Mr. Dunn added that to "reverse the traditional policy of the Food and Drug law of this country by making intent an essential ingredient of the offense * * * would emasculate this law * * *" (*ibid.*). Moreover, Mr. Dunn commented

[15] See, *e.g.*, Hearing before a Subcommittee of the Senate Committee on Interstate and Foreign Commerce, on S. 1190 and H.R. 4071, 80th Cong., 2d Sess., pp. 70–71.

"That is good" when Senator McMahon quoted a pertinent excerpt from the Court's opinion in *Dotterweich* during the hearings (*id.* at 49–50).

Nonetheless after these hearings the Senate passed a bill amending Section 303(a) of the Act to impose criminal liability only for violations committed "willfully or as a result of gross negligence." 4 Cong. Rec. 6760–6761 (June 1, 1948). However, the amendment was subsequently stricken in conference. 94 Cong. Rec. 8551 (June 17, 1948); 94 Cong. Rec. 8838 (June 18, 1948). Thus, Congress specifically refused to alter the standard of criminal liability imposed by the 1938 Act as construed by this Court in *Dotterweich*. It remained unchanged until the decision of the court of appeals in the present case.

C. THE 1938 ACT CONTEMPLATES REASONABLE EXERCISE OF PROSECUTORIAL DISCRETION IN ITS ADMINISTRATION

In enacting the 1938 Act Congress recognized that the strict standards of liability created might operate harshly, or even unfairly. Congress therefore expressed its concern that minor violations of the Act should not be subjected to criminal prosecution. Thus, Section 306 of the Act, 21 U.S.C. 336, provides that:

> Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

This provision indicates that FDA was expected to exercise reasonable discretion in invoking the Act's

criminal sanctions. Accordingly, the Court observed in *Dotterweich* that fair enforcement of the Act "must be trusted" in part to "the good sense of prosecutors." 320 U.S. at 285.

In exercising the reasonable prosecutorial discretion contemplated by Congress and this Court, FDA has applied criteria which do not result in criminal prosecutions for every violation of the statute's strict standard of criminal liability. The government is interested in the prevention and correction of conditions potentially dangerous to the public health and welfare, not in prosecution for its own sake. Accordingly, FDA's standards for reference of cases to the Department of Justice for prosecution embrace the following categories: continuing violations of law (*e.g.*, continuing insanitary conditions in a food plant); violations of an obvious and flagrant nature (*e.g.*, food warehouse overrun with rodents, birds and insects, which contains plainly contaminated products); and intentionally false or fraudulent violations.

The standard for prosecution of individual corporate officials, as distinguished from the prosecution of their corporations, is based on the reasonable relationship criterion of *Dotterweich*. The government's policy is to prosecute only those individuals who are in a position and who have an opportunity to prevent or correct violations, but fail to do so. Officials who lack authority to prevent or correct violations, or who were totally unaware of any problem and could not have been expected to be aware of it in the reasonable exercise of their corporate duties, are not the subject of criminal action. Even if investigation discloses the ele-

ments of liability, and indicates that an official bears a responsible relationship to them, the agency will not ordinarily recommend prosecution unless that official, after becoming aware of possible violations, often (as with Park) as a result of notification by FDA, has failed to correct them or to change his managerial system so as to prevent further violations.[16] In those instances where prosecution is brought, it is brought for past, as well as most recent, violations.

D. THE PROSECUTION OF PARK WAS REASONABLE AND HIS CONVICTION IS SUPPORTED BY THE EVIDENCE

The government's decision to prosecute Park personally, as well as Acme, was in conformity with the guidelines just discussed. The massive rodent infestation of Acme's warehouses is scarcely a minor or technical violation of the 1938 Act. It is a potential health hazard.[17] As FDA stated to Park in its letter of January 1972, the "reprehensible conditions [of the Baltimore warehouse] obviously existed for a prolonged period of time without any detection, or were completely ignored" (A. 64).

[16] FDA has adopted an elaborate system of internal review and enforcement guidelines, and also offers a hearing, even though one is not required, so that suspects can explain the situation before a prosecution is recommended. The review requires approval by the FDA Regional Directors, the compliance division of the relevant bureau (e.g., Bureau of Foods), the Regulatory Management Staff in the office of the Associate Commissioner for Compliance and the Assistant General Counsel, Food and Drugs Division, Department of Health, Education, and Welfare.

[17] The hazard of insanitary food storage is indicated by the following observation in Levy and McIntire, *The Economic Impact of a Food-Borne Salmonellosis Outbreak*, American Medical Association Journal, Vol. 230, No. 9 (December 2, 1974), p. 1281:

"Approximately five food-borne disease outbreaks of this size [125 persons] and numerous other cases of food-borne illness, are reported and investigated every year in Minnesota. In addition, many other cases are thought to go unrecognized as food-borne illness or to be recognized but not reported to health departments. The total economic loss from this food-borne illness no doubt amounts to hundreds of thousands of dollars a year. Greater expenditure for effective preventive measures, at relatively low costs, could have dramatic effects on reducing the occurrence of food-borne illness and its considerable economic impact."

Moreover, Park personally had received a letter from FDA in April 1970 advising him of serious rodent infestation in Acme's Philadelphia warehouse (A. 70–71). And in its letter of January 27, 1972, FDA informed Park of the unwholesome conditions revealed in the Baltimore warehouse by the November–December 1971 inspection.[18] Park nevertheless failed to take adequate steps to correct these conditions. After merely being generally assured by another subordinate in January 1972 that Mr. McCahan would take corrective action, Park concluded that there was nothing more he could have done constructively (A. 47). He simply passed FDA's report on to his subordinates, as if he had no personal responsibility to require effective measures to put an end to the serious

[18] The November-December 1971 inspection revealed, among other things, that the warehouse was heavily infested with rodents, buildings were open to rodent and bird entry due to poor fitting and damaged doors and broken windows; trash and damaged merchandise was found between and behind stored food; food was stored against walls and so close together that inspection was difficult or impossible; stock was not rotated and lighting was so insufficient in some areas that employees could

existing violations of the Act that had been brought to his attention.[19]

Although his subordinates took steps that partially corrected these conditions (A. 23), the agency's March

not see defiled merchandise; and that, as a result of these and other insanitary conditions, 150,000 lbs. of food products were rodent-defiled and had to be destroyed (see *supra*, pp. 4–5).

[19] There were a number of constructive actions he should have taken. With the list of observations before him, he could have applied his own common sense to the situation and personally ordered corrective action. He could have, for instance, demanded that the warehouse be completely emptied and cleaned, that each lot of food be moved and checked thoroughly for rodents, and that the structure be thoroughly checked to make sure that all possible points of rodent entry be closed. Such measures are elementary methods of housecleaning.

At the very least, respondent should have personally discussed with McCahan the list of observations item by item and ascertained precisely what McCahan would do about each. He could have demanded to know why the Baltimore facility had been allowed to deteriorate to the point that it had. He could have attempted to ascertain the amount of effort and money that would be necessary to insure that the premises would be cleaned up properly and offered McCahan whatever assistance was necessary. Any one or all of these things would have impressed upon McCahan the importance which he attached to the situation. He could also have instructed the appropriate corporate officials to utilize the resources necessary to remedy the situation. Certainly respondent could have followed up by calling McCahan and other corporate officials who handled sanitation problems to get personal briefings on the specific corrections being made. Indeed, given the fact that these same employees had already failed twice in the recent past, respondent could have retained a reputable outside consultant familiar with FDA requirements. Nor would it have been unreasonable for respondent to have personally visited the Baltimore warehouse to see for himself what progress, if any, was being made in correcting the situation. Finally, he could have closed the warehouse down unless and until he was personally satisfied that it had, beyond any doubt, been cleaned up. Given respondent's apathetic behavior, it is not surprising that the necessary steps were not taken and that many of the conditions went uncorrected until a criminal prosecution was instituted.

1972 inspection revealed that serious sanitation problems continued to exist in the Baltimore warehouse. Only then did FDA recommend prosecution of Park, as well as the corporation, for the specific violations found in November and December 1971 and in March 1972.

The evidence warranted Park's conviction. Park acknowledged that, as Acme's chief executive officer, he was "responsible for the entire organizational structure" and he agreed with the prosecutor's statement that "if a system that is set up and it doesn't work, you are responsible for changing it" (A. 55). Park was advised in April 1970 (with respect to the Philadelphia warehouse) and again in January 1972 (with respect to the Baltimore warehouse) that his system for controlling sanitation problems had failed, and Park conceded that "the fact that this occurrence occurred in Baltimore indicated that it wasn't working perfectly" (A. 55). In these circumstances, the jury was justified in concluding that Park bore a "responsible relation" to the insanitary conditions of the Baltimore warehouse.

E. THE COURT OF APPEALS' STANDARD WOULD TEND TO DEFEAT THE PUBLIC HEALTH PURPOSE OF THE ACT'S CRIMINAL PROVISIONS

The 1938 Act imposes "the highest standard of care on [food] distributors," because "the public interest in the purity of its food is so great" (*Smith* v. *California, supra,* 361 U.S. at 152). Despite these stringent

standards, insanitary conditions in the food industry remain a serious problem. Indeed, more than 90 percent of the legal actions brought by FDA under the 1938 Act concern insanitary conditions in food establishments. Notwithstanding these efforts, in a 1972 special report to Congress the General Accounting Office concluded that sanitary conditions in the food industry in the United States were deteriorating. It found in a survey limited to manufacturing and processing establishments that, as of 1972, 40 percent of the plants surveyed were operating under insanitary conditions, and 24 percent were seriously insanitary. It recommended an increase in FDA's enforcement effectiveness.[20] In response, Congress has substantially increased FDA appropriations for food establishment inspection and enforcement.

The lower standards of public accountability adopted by the court of appeals in the present case would seriously impair FDA's efforts to correct this serious problem and would substantially frustrate the purpose of the 1938 Act. To be effective against the growing problem of insanitary conditions the law must be effective against supermarket chains, such as Acme. Supermarket sales in the United States in 1973 exceeded 56.3 billion dollars. And supermarket chain stores accounted for 49.8 percent of all supermarket sales in that year. Among supermarket chains in the United States, Acme is the fourth largest with sales in 1973 exceeding 2.3 billion dollars. See *Progressive Grocer*, April 1974; see also, National Commission on Food Marketing, *Organization and Competition in Food Retailing* (1966).

[20] Comptroller General of the United States, *Dimensions of Insanitary Conditions in the Food Manufacturing Industry*, Report to the Congress, No. B–164031(2) (April 18, 1972).

Yet the holding below would weaken the law in relation to large corporate entities such as supermarket chains by making the prosecution of responsible corporate officials more difficult. Prosecution of such large corporations without the inclusion of responsible individuals has relatively little deterrent effect.[21] It is precisely because responsibility may be disbursed and diluted within a large firm's bureaucracy that the statute imposes liability on senior corporate officials in order to motivate them to anticipate and prevent problems or to seek them out and have them corrected. See discussion, *supra*, p. 20–23 The holding below, however, by requiring "wrongful action," and (under *Abbott*) knowledge of it, would encourage individual corporate officials to avoid knowledge and to insulate themselves from information that might show a violation of the law. High corporate officials, best situated to require preventive measures, would be encouraged to delegate

[21] See, *e.g.*, the National-American Wholesale Grocers' Association, *Warehouse Sanitation Manual* 106 (1972 ed.):

"A. A TOTAL COMMITMENT BY TOP MANAGEMENT

"This is the obvious and absolute must. Nothing less than a total commitment will suffice * * *.

* * * because it is top management whose neck is on the chopping block should the FDA axe fall;

* * * because a no-nonsense sanitation policy can only be effected and perpetuated down through the ranks if it has the top man's full sanction, personal involvement, and complete support."

their responsibility to lower officials, and those individuals would in turn undoubtedly seek to place the responsibility elsewhere. By contrast, the Act's strict standard of criminal liability, properly applied here by the district court, gives executives a personal incentive to seek out the problems within the company and to have them corrected.

Moreover, the court of appeals' standard would place an impractical burden of proof on the government. Even where a corporate official knows, in general terms, about a problem of insanitary conditions in a food warehouse, he is unlikely to know about any of the details, and thus may not knowingly or willfully have caused the specific violations involved. Even the local warehouse manager would not necessarily know that a particular lot of flour or breakfast cereal was contaminated, even though he might very well know about the general insanitary conditions of the warehouse. Unless a standard of strict criminal liability is imposed, therefore, in most instances, the very officials responsible for maintaining compliance with the law, and who possess the corporate authority to assure compliance, would simply escape liability for lack of detailed proof.

The larger the enterprise, the less effective would the government's enforcement capabilities become. In order to assure the high degree of accountability envisioned by Congress when the law was enacted, strict criminal liability is even more important today than it was in 1938, when the food industry was characterized by smaller firms.

Finally, as we have noted (*supra,* p. 13), the strict standards of the 1938 Act, as interpreted by *Dotterweich,* are of pervasive importance to the public health because the same standards of care and the same penal provisions at issue here govern the distribution of life-threatening and life-saving drugs and medical devices, as well as food.

II. EVIDENCE OF PRIOR INSANITARY CONDITIONS AT ANOTHER WAREHOUSE WAS ADMISSIBLE TO REBUT PARK'S DEFENSE OF GOOD FAITH RELIANCE ON HIS SUBORDINATES

In its case-in-chief the government established that Acme's system of sanitation control required the cooperation of several different corporate officials and that Park was responsible for seeing that all these individuals worked together. See testimony of Dr. Norman Kramer (A. 30–34); Robert McCahan (A. 34–39); and A. E. Gilfillan (A. 39–42). See also Statement, *supra.*

Park testified in his own defense that he had employed a system in which he relied upon his subordinates, and that he was ultimately responsible for this system. He further testified that he had found these subordinates to be "dependable" and had "great confidence" in them (A. 49; Tr. 166). Accordingly, the jury might have inferred from Park's testimony that his subordinates, and not he, should be held responsible since the sanitation duties had been delegated to them and he had no reason to suspect they were failing to get the job done.

On cross-examination, the government established that twenty months before discovery of the insanitary

conditions at the Baltimore warehouse, FDA had sent a letter to Park advising him of insanitary conditions at the firm's Philadelphia warehouse. The purpose of this line of questioning was to show that Park was on notice that he could not rely upon his system of delegation to subordinates to prevent insanitary conditions at the firm's warehouses and that he was aware of the deficiencies of this system before the Baltimore violations were discovered. Park admitted that he had the responsibility and the power to take whatever steps were necessary to insure that the firm's system for handling sanitation problems worked in compliance with the Act (A. 54–55).

The court of appeals viewed this evidence as if it were evidence of an unprosecuted prior crime, the admissibility of which depended on a balancing of prejudice to the defendant against the needs of justice. See *United States* v. *Woods, supra,* 484 F. 2d at 134–135.[22] It found that the evidence was prejudicial and that no need for it had been shown under the theory on which the case was tried. The evidence demonstrated, however, both Park's awareness of prior sanitation deficiencies in Acme's warehouse system and his admitted responsibility for correcting them. This testimony was therefore relevant to the issue of Park's "responsible relationship" to the violations since it served to rebut his defense that he had justifiably

[22] In *Woods*, the defendant was charged with first degree murder of an infant. The court held that evidence that other children in her care had died or had suffered respiratory problems was admissible to prove that the crime charged had in fact been committed.

relied upon subordinates to handle sanitation matters.

This testimony was not offered by the government during its case in chief; it was elicited from Park in response to his testimony on direct examination. Such a procedure is appropriate when a defendant "introduces evidence in his own behalf after his motion for acquittal has been overruled." *United States* v. *Calderon,* 348 U.S. 160, 164. For example, in *United States* v. *Ross,* 321 F 2d 61, 67 (C.A. 2), certiorari denied, 375 U.S. 894, the defendant in a prosecution for securities fraud testified on direct examination that he was "an unwitting tool" in the fraud. The court held that the government could elicit testimony on cross examination establishing that the defendant "had long drifted among [brokerage] houses selling similarly worthless stock by similar methods." *Id.* at 67. See also, *United States* v. *Kaufman,* 453 F. 2d 306 (C.A. 2); *United States* v. *Purin,* 486 F. 2d 1363 (C.A. 2), certiorari denied, 417 U.S. 930; *United States* v. *Wright,* 466 F. 2d 1256 (C.A. 2), certiorari denied, 410 U.S. 916.[23]

The testimony concerning the sanitation problem at the Philadelphia warehouse was not offered to show that Park had a propensity to commit criminal acts or, as in *United States* v. *Woods, supra,* to show that

[23] Cf. *Walder* v. *United States*, 347 U.S. 62 (evidence of prior arrest for possession of narcotics admissible to impeach defendant's testimony); *Michelson* v. *United States*, 335 U.S. 469 (a defense character witness may be cross-examined concerning his knowledge of defendant's prior criminal activities); *Williamson* v. *United States*, 207 U.S. 425 (evidence of prior criminal acts admissible to establish guilty intent, design, purpose or knowledge).

the crime charged had been committed. Rather it was offered to show that Park's alleged reliance on his subordinates could not have been justifiable. This testimony was therefore directly relevant to the jury's determination of whether respondent shared the responsibility for the insanitary condition of the firm's Baltimore warehouse.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the judgment of the court of appeals should be reversed.

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JANUARY 1975.

U.S. GOVERNMENT PRINTING OFFICE: 1974